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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/089,009

08/06/2002

Carolyn K. Goldman

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10/18/2005

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EXAMINER

JIANG, DONG

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 10/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,009

Applicant(s)

GOLDMAN ET AL.

Examiner

Dong Jiang

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-5, 9, 11-15 and 22-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-5, 9, 11-15 and 22-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED OFFICE ACTION

The request filed on 19 September 2005 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/089,009 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 17 June 2005 is acknowledged and entered. Following the amendment, claim 10 is canceled, claims 1, 3, 9 and 13 are amended, and the new claims 24 and 25 are added.

Currently, claims 1, 3-5, 9, 11-15 and 22-25 are pending and under consideration.

Declaration

The Declaration by Dr. Waldmann under 37 CFR 1.132 filed on 17 June 2005 is insufficient to overcome the prior art rejection of claims 1, 3-5, 9, 10, 13-15, 22 and 23 based upon Colamonici et al. (J. Immunol., 1990, 145:155-160) under 35 U.S.C. 102(b), or, in the alternative, under 35 U.S.C. 103(a) as set forth in the last Office action because for the following reasons.

The Declaration indicates that the Colamonici reference discloses the use of mAb anti-Tac and 7G7/B6 (both recognize epitopes of the α chain of IL-2R) to immunoprecipitate IL-2R α and polypeptides associated therewith, including the 37 kDa and 20 kDa polypeptides, whereas the inventors of the instant application demonstrates that when cell lysates are first pre-cleared with anti-Tac to remove all components which may bind to the anti-Tac antibody, and then are immunoprecipitated with the 5F7 antibody (recognizing the two polypeptides of the present invention), demonstrating that the 32-34 kDa and 26-28 kDa ILRAPs of the present invention are not recognized by the anti-Tac mAb in the pre-clearing step (items 4-6). The declaration further indicates that the presence of ILRAPs can be demonstrated in a particular cell line where IL-2Ra is not expressed, and therefore, these polypeptides cannot be recognized by anti-Tac and 7G7/B6 mAb, but are recognized by the 5F7 mAb, indicating that Colamonici's polypeptides are not capable of forming a complex with the 5F7 (item 7). These are not persuasive because, with

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respect to applicants demonstration that the 32-34 kDa and 26-28 kDa ILRAPs of the present invention are not recognized by the anti-Tac, it is irrelevant because nowhere in the Colamonici reference indicates that the 37 kDa and 20 kDa polypeptides are recognized by anti-Tac mAb neither, and the pre-clearance with anti-Tac would not eliminate possible free form of the polypeptides that were not associated with the IL-2R α at the time the pre-clearing step occurred. Further, the declaration (items 6 and 7) does not identify the cells used in the experiments, therefore, one cannot judge whether they are the same as Colamonici's. With respect to applicants conclusion that Colamonici's polypeptides are not capable of forming a complex with the 5F7, it is unclear based on what such a conclusion could be drawn as neither the applicant nor Colamonici has ever tested such, or provided any relevant information regarding such. Further, the declaration provides no actual experimental evidence such that the examiner can independently draw conclusions. Therefore, the declaration is insufficient to overcome the instant rejection.

Withdrawal of Objections and Rejections:

All objections and rejections of claim 10 are moot as the applicant has canceled the claim.

The objection of claim 13 is withdrawn in view of applicant's amendment.

Rejections under 35 U.S.C. 112:

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-5, 9, 11-15, 22 and 23 remain rejected, and the new claims 24 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the previous Office Actions mailed on 03 June 2004, and 19 April 2005.

Applicants argument filed on 17 June 2005 has been fully considered, but is not deemed persuasive for reasons below.

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At page 6 of the response, the applicant argues that claims 1 and 3, as amended, are directed to an IL-2R associated polypeptide defined not only by its molecular weight, but also by its ability to form a complex with the specific monoclonal antibody (PTA-82), that it is well established that a mAb is a single type of antibody directed against a single specific epitope on an antigen, and thus, any polypeptide capable of forming a complex with the antibody and has a MW of about 32 to 34 kDa or about 26-28 kDa is an IL-2R associated polypeptide, and that one of ordinary skill in the art would understand the meets and bounds of the claims. This argument is not persuasive because, as addressed in the previous Office Action, polypeptides with distinct structures may have the same MW and share the same epitops as that of the present polypeptides since an epitope merely requires a minimum of 5-7 amino acids, which is also well established. As such, the claims, as written, encompass polypeptides with unknown structures, and there is no way for a skilled artisan to determine the meets and bounds of the claimed polypeptides merely based upon the MW and one single epitope. Therefore, the claims are not adequate for pointing out that which applicants see as their invention. Additional limitation such as the source of the polypeptide would overcome the rejection. Claims 24 and 25 are similarly indefinite.

Applicants further argue, on page 6 of the response, that claim 9 has been amended to include the method steps (a)-(c). Applicants argument has been fully considered, but is not deemed persuasive because, as addressed in the last Office Action mailed on 6/3/04, claim 9 is still incomplete for omitting essential method steps of the process. The preamble of the claim recites "a method for purifying ...", whereas the method steps are merely up to forming a complex (step (c)), which is not complete, nor sufficient to allow the achievement of the goal for purifying the polypeptide set forth in the preamble.

The remaining claims remain rejected for depending from an indefinite claim.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-5, 9, 13-15, 22 and 23 remain rejected, and the new claims 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by, or, in the alternative, under 35 U.S.C. 103(a) as obvious over Colamonici et al. (J. Immunol., 1990, 145:155-160), for the reasons of record set forth in the previous Office Action mailed on 03 June 2004, and 19 April 2005.

Applicants argument filed on 17 June 2005 has been fully considered, but is not deemed persuasive for reasons below.

At page 7 of the response, the applicant argues, based on the Declaration by Dr. Waldmann, that the claimed polypeptides are present in lysates from cells recognized by the anti Tac mAb that have been pre-cleared with anti-Tac, that a cell line capable of forming a complex with the 5F7 mAb (PTA-82), but cannot form a complex with either anti-Tac or 7G7/B6 as this cell line does not express IL-2R α , strongly suggesting Colamonici's polypeptides are not capable of forming a complex with 5F7 mAb, and are not the same polypeptides as that claimed. This argument is not persuasive for the same reasons above addressed under "Declaration".

At pages 7-8 of the response, Applicants argue that a person of ordinary skill in the art would not consider a 37 kDa protein to be a polypeptide having a MW of about 32-34 kDa, and such a size difference is significant, and that, citing the case law, anticipation under 102 can be

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found only when a reference discloses exactly what is claimed, and thus the Colamonici reference does not disclose the subject matter of the pending claims. This argument is not persuasive because, given the fact that Colamonici's polypeptides and polypeptides of the present invention are isolated from the same sources, and have the same functional property (associated with IL-2R), and given the nature of the method (SDS-PAGE) used for determining the MW (as addressed in the last Office Action), the difference in MW can be easily explained by experimental variations in the absence of evidence to the contrary, as the method of SDS-PAGE, depending upon, for example, the gel concentration and running time, can give results with slight difference in MW for the same molecule in different experiments. Therefore, such argument is not sufficient to support the conclusion that the Colamonici polypeptides and the presently claimed polypeptides are distinct molecules in the absence of other evidence such as sequence structure and/or different sources of isolation. Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on (*In re Best, Bolton, and Shaw*, (CCPA) 195 USPQ 430).

At page 8 of the response, the applicant argues that the Colamonici reference also does not render obvious the subject matter of the pending claims due to the same reasons presented earlier. Applicant's argument has been fully considered, but is not deemed persuasive for the same reasons above.

Conclusion:

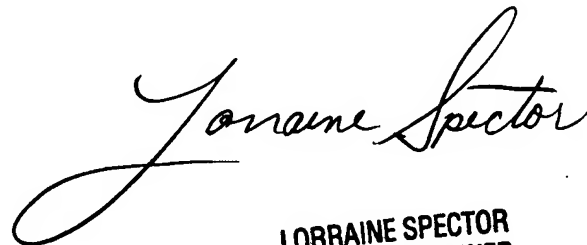
No claim is allowed.

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Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on 571-272-0829. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

A handwritten signature in cursive script that reads "Lorraine Spector".

LORRAINE SPECTOR
PRIMARY EXAMINER

Dong Jiang, Ph.D.
Patent Examiner
AU1646
10/4/05